K043035

JUL 11 2005

genzyme

7 510(K) SUMMARY (AS REQUIRED BY 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Genzyme Corporation is providing a summary of the safety and effectiveness information available for Sepragel™ ENT Bioresorbable packing/stent (Sepragel™ ENT).

7.1 Sponsor/Applicant Name and Address:

Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

7.2 Sponsor Contact Information:

Barbara Pizza
Manager, Regulatory Affairs
Phone: 617.252.7953
FAX: 617.761.8414
email: barbara.pizza@genzyme.com

7.3 Date of Preparation of 510(k) Summary:

Date

7.4 Device Trade or Proprietary Name:

Sepragel™ ENT Bioresorbable Packing/Stent

7.5 Device Common/Usual or Classification Name:

Ear, nose and throat synthetic polymer material

7.6 Identification of the Legally Marketed Devices to which Equivalence is Being Claimed:

510(k) Number	Name of Predicate Device	Name of Manufacturer (Town, State)
K012532 (K993362)	Sepragel™ Sinus	Genzyme Corporation Cambridge, MA
K001148 (K002972)	MeroGel™ Nasal Otologic Pack (MeroGel™ Control Gel ENT Surgical Dressing)	Medtronic Xomed Jacksonville, FL

7.7 Device Description:

Sepragel ENT is a sterile, non-pyrogenic, transparent, viscoelastic, bioresorbable gel composed of cross-linked molecules of hyaluronan. It is indicated for use in patients undergoing nasal/sinus, middle ear and external ear canal surgery as a space-occupying dressing and/or gel stent intended to separate and prevent adhesions between mucosal

surfaces, to help control minimal bleeding following surgery or trauma, and act as an adjunct to aid in the natural healing process.

Sepragel™ ENT hylan B gel, is a sterile, non-pyrogenic, transparent, viscoelastic gel composed of cross-linked molecules of hyaluronan. This hyaluronan is a bioresorbable material that functions to fill the sinus cavity, middle ear and external ear canal following surgery and to keep mucosal surfaces separate during the healing process. During this time, the tamponade effect helps control minimal bleeding normally associated with routine Otologic surgery. Sepragel ENT leaves the site of placement by natural elimination. In nasal/sinus applications it may be aspirated from the cavity earlier at the discretion of the physician.

7.8 Intended Use:

Sepragel ENT packing/stent is indicated for use in patients undergoing nasal/sinus, middle ear and external ear canal surgery as a space-occupying dressing and/or stent intended to prevent adhesions in the nasal cavity, separate mucosal surfaces, help control minimal bleeding following surgery or trauma, and act as an adjunct to aid in the natural healing process. The device is indicated for use in the middle ear following canalplasty, myringoplasty, tympanoplasty, stapes and mastoid surgery. The device is indicated following nasal/sinus surgery or trauma to prevent lateralization of the middle turbinate during the post operative period.

7.9 Comparison of Technological Characteristics of Sepragel™ ENT with Legally Marketed Devices:

Table 4 is the Table of Similarities and Differences between Genzyme's Sepragel™ ENT Bioresorbable Packaing/Stent and the legally marketed devices identified in **Section 7.6**.

Table 4: Comparison to Marketed Devices

	Sepragel™ ENT Genzyme Corporation PROPOSED	Hylasine™ (Sepragel Sinus) Genzyme Corporation (K993362, K012532)	MeroGel™Nasal Dressing/Sinus Stent and Otologic Packing Medtronic Xomed (K001148)
Device Name	ENT synthetic polymer material	Epistaxis balloon/Intranasal Splint	Epistaxis balloon/ ENT synthetic polymer material
Product Code	77KHJ	77EMX/LYA	77KHJ
Intended Use/Indication	For use in patients undergoing nasal/sinus surgery as a space-occupying gel stent to separate and prevent adhesions between mucosal surfaces in the nasal cavity, to help control minimal bleeding following surgery or nasal trauma, and to prevent lateralization of the middle turbinate during the postoperative period. The device is also indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty and, and stapes and mastoid surgery.	For use in patients undergoing nasal/sinus surgery as a space-occupying gel stent to separate and prevent adhesions between mucosal surfaces in the nasal cavity, to help control minimal bleeding following surgery or nasal trauma, and to prevent lateralization of the middle turbinate during the postoperative period.	MeroGel Otologic Pack is a space occupying dressing and/or stent intended to separate mucosal surfaces, help control minimal bleeding and act as an adjunct to aid in the natural healing process. The device is indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty and, and stapes and mastoid surgery.
Material Composition	Derivative hyaluronic acid	Derivative hyaluronic acid	Derivative hyaluronic acid
Bioresorbable	YES	YES	YES
Product matrix	Gel in a syringe	Gel in a syringe	Non-woven pad in a protective folded sheet

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2005

Genzyme Corporation
c/o Barbara Pizza
Manager Regulatory Affairs
55 Cambridge Parkway
Cambridge, MA 02142

Re: K043035
Trade/Device Name: Sepragel™ ENT Nasal/Sinus and Otologic Dressing
Regulation Number: 21 CFR 874.3620
Regulation Name: ENT synthetic polymer material
Regulatory Class: Class II
Product Code: KHJ
Dated: June 17, 2005
Received: June 20, 2005

Dear Ms. Pizza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): New Application

Device Name: Sepragel™ ENT Bioresorbable Packing/Stent

Indications for Use:

Sepragel ENT packing/stent is indicated for use in patients undergoing nasal/sinus, middle ear and external ear canal surgery as a space-occupying dressing and/or stent intended to prevent adhesions in the nasal cavity, separate mucosal surfaces, help control minimal bleeding following surgery or trauma, and act as an adjunct to aid in the natural healing process. The device is indicated for use in the middle ear following canalplasty, myringoplasty, tympanoplasty, stapes and mastoid surgery. The device is indicated following nasal/sinus surgery or trauma to prevent lateralization of the middle turbinate during the post operative period.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K053035